K132675

510(k) Summary of Safety and Effectiveness

Summary Date: August 23, 2013

Submitter: CeloNova BioSciences, Inc.
18615 Tuscany Stone, Ste. 100
San Antonio
Texas 78258, USA

OCT 0 3 2013

Contact : Nicole C. Barber
Manager, Regulatory Affairs

1. Common name, Trade name & Classification of Subject Device

Trade Name :	Embozene® Microspheres
Common Name(s) :	Vascular Embolization device, embolization, arterial
Product Code:	KRD, 21 CFR 870.3300
Classification:	Class II

2. 510(k) Number and Product Code of Predicate Device

Trade Name:	Embozene® Microspheres
Manufacturer:	CeloNova BioSciences, Inc.
510(k) Number:	K073417
Product Code:	KRD, 21 CFR 870.3300

3. Indications for Use and Intended Purpose

Embozene® Microspheres are intended for embolization of hypervascular tumors and arteriovenous malformations.

4. Device Description

Embozene® Microspheres are tightly calibrated, compressible microspheres intended to occlude vasculature for the purpose of blocking blood flow to a target tissue such as hypervascular tumor (HVT) or arteriovenous malformation (AVM). Embozene® Microspheres are manufactured from sodium polymethacrylate and coated with proprietary Polyzene®-F. The

microspheres are compressible to enable smooth delivery through the indicated delivery catheter. Embozene® Microspheres are color coded by size to allow easy identification of different sizes.

Embozene® Microspheres are supplied sterile and packaged in 20ml polycycloolefin syringes with a standard 7ml fill volume across the range. Embozene® Microspheres syringes and vials are available with 1 ml or 2 ml microsphere volume per syringe or vial. Product configurations are shown in the Tables below.

Product REF Codes for Embozene Color-Advanced Microspheres in Syringe and Vial

Product REF Codes Embozene® Color-Advanced Microspheres		***Volume of Color Embozene® Microspheres per Syringe***		***Volume of Color Embozene Microspheres per Vial***	
Nominal Size	Specifications	1ml	2ml	1ml	2ml
40 µm	40 µm ±10 µm	10410-S1	10420-S1	10401-V1	10402-V1
75 µm	75 µm ±15 µm	10710-S1	10720-S1	10701-V1	10702-V1
100 µm	100 µm ±25 µm	11010-S1	11020-S1	11001-V1	11002-V1
250 µm	250 µm ± 50 µm	12010-S1	12020-S1	12001-V1	12002-V1
400 µm	400 µm ± 50 µm	14010-S1	14020-S1	14001-V1	14002-V1
500 µm	530 µm ± 50 µm	15010-S1	15020-S1	15001-V1	15002-V1
700 µm	700 µm ± 50 µm	17010-S1	17020-S1	17001-V1	17002-V1
900 µm	900 µm ± 75 µm	19010-S1	19020-S1	19001-V1	19002-V1
1100 µm	1100 µm ± 75 µm	111010-S1	111020-S1	111001-V1	111002-V1
1300 µm	1300 µm ± 75 µm	113010-S1	113020-S1	113001-V1	113002-V1

Product REF Codes for Embozene Opaque (Non-Colored) Microspheres in Syringe and Vial

Product REF Codes Embozene® Opaque Microspheres		***Volume of Opaque Embozene® Microspheres per Syringe***		***Volume of Opaque Embozene Microspheres per Vial***	
Nominal Size	Specifications	1ml	2ml	1ml	2ml
40 µm	40 µm ±10 µm	10410-S0	10420-S0	10401-V0	10402-V0
75 µm	75 µm ±15 µm	10710-S0	10720-S0	10701-V0	10702-V0
100 µm	100 µm ±25 µm	11010-S0	11020-S0	11001-V0	11002-V0
250 µm	250 µm ± 50 µm	12010-S0	12020-S0	12001-V0	12002-V0
400 µm	400 µm ± 50 µm	14010-S0	14020-S0	14001-V0	14002-V0
500 µm	530 µm ± 50 µm	15010-S0	15020-S0	15001-V0	15002-V0
700 µm	700 µm ± 50 µm	17010-S0	17020-S0	17001-V0	17002-V0
900 µm	900 µm ± 75 µm	19010-S0	19020-S0	19001-V0	19002-V0
1100 µm	1100 µm ± 75 µm	111010-S0	111020-S0	111001-V0	111002-V0
1300 µm	1300 µm ± 75 µm	113010-S0	113020-S0	113001-V0	113002-V0

5. Similarities and Differences to Predicate device

The intended use of the subject device remains unchanged as compared to the predicate. The subject device and the predicate have the same design, specifications, fundamental scientific technology, and packaging. The only change is the addition of 1100 µm and 1300 µm sizes of Embozene® Microspheres. The additional sizes are available in gray and pink colors, respectively. The colorants used to create those colors are the same as those used in the predicate.

6. Summary of Technological Characteristics

Comparison between the Subject Device (Embozene®) and the Predicate Device (Embozene®)

Point of Comparison	Embozene® Subject		Embozene® Predicate	
Chemical composition	unchanged			
Osmolarity of transport solution	unchanged			
pH of transport solution	unchanged			
Size Range and Colors	40 ± 10 µm 75 ± 15 µm 100 ± 25 µm 250 ± 50 µm 400 ± 50 µm 500 ±50 µm 700 ± 50 µm 900 ± 75 µm 1100 ± 75 µm 1300 ± 75 µm	Black Burgundy Orange Yellow Blue Red Green Purple Gray Pink	40 ± 10 µm 75 ± 15 µm 100 ± 25 µm 250 ± 50 µm 400 ± 50 µm 500 ±50 µm 700 ± 50 µm 900 ± 75 µm	Black Burgundy Orange Yellow Blue Red Green Purple
Color Availability	Color or opaque		Color or opaque	
Sterility	Pyrogen-free, sterile		Pyrogen-free, sterile	
Packaging	Syringe or vial		Syringe or vial	
Syringe total fill volume	7ml		7ml	
Microsphere volume per syringe	1 or 2 ml		1 or 2 ml	
Shelf life	3 years		3 years	
Indication for Use	Hypervascularized Tumors, Arteriovenous Malformations		Hypervascularized Tumors, Arteriovenous Malformations	

7. Summary of In-Vitro Testing

Size distribution and catheter compatibility testing were conducted on the subject device and concluded to be equivalent to the predicate.

8. Summary of Clinical Experience

The clinical evaluation included in the 510(k) reviews Transarterial Embolization (TAE) using various embolic agents to physically occlude vessels to restrict blood flow over the last ten years. The overall review of the scientific literature, unpublished data and post market surveillance, indicate that Embozene® Microspheres including 1100 µm and 1300 µm are reasonably safe and effective for the treatment of hypervascular tumors and arteriovenous malformations. Therefore, it could be concluded that the benefits of TAE with Embozene microspheres family including the additional 1100 and 1300 µm microspheres for the treatment of hypervascular tumors and arteriovenous malformations outweigh the potential risk when used within their labeled application.

9. Summary

The subject device and the predicate have the same indications for use, design, and fundamental scientific technology. The subject device Embozene® Microspheres with the addition of 1100 µm and 1300 µm sizes are substantially equivalent to the cleared Embozene® Microspheres (K073417).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 3, 2013

CeloNova BioSciences, Inc.
C/O Nicole C. Barber, RAC
Manager, Regulatory Affairs
18615 Tuscany Stone
Suite 100
San Antonio, TX 78258

Re: K132675
Trade/Device Name: Embozene® Microspheres
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: September 2, 2013
Received: September 4, 2013

Dear Ms. Barber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

K132675

Indications for Use Statement

510(k) Number (if known) _____

Device Name **Vascular Embolization Device**

Indications for Use **Embozene® Microspheres are indicated for the embolization of hypervascular tumors and arteriovenous malformations.**

Prescription Use___X_____ AND/ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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